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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/757,708 | 01/14/2004 | Derek O' Hagan | PP-19768.002 | 3852 |

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EXAMINER

POPA, ILEANA

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/757,708

Applicant(s)

O' HAGAN ET AL.

Examiner

Ileana Popa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48, 50, 52-64, 69 and 72-89 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-48, 50, 52-64, 69, and 72-89 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 49, 51, 65-68, 70, and 71 have been cancelled.

New claims 72-89 were added.

Claims 1-48, 50, 52-64, 69, 72-89 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 19-22, 72-75, 84, and 85, drawn to microparticles comprising a biodegradable polymer, a cationic surfactant, a first polynucleotide-containing species, and a species entrapped within the microparticles, classified in class 514, subclass 44.
 - II. Claims 23-26, 76-79, 86, and 87, drawn to microparticles comprising a biodegradable polymer, a cationic surfactant, a first polynucleotide-containing species, and a species adsorbed to the microparticles, classified in class 514, subclass 44.
 - III. Claims 32, 33, 80-83, 88, and 89, drawn to microparticles comprising a biodegradable polymer, a cationic surfactant, and a first polynucleotide-containing species, wherein a first portion of the cationic surfactant is bound to the polymer and the second portion forms a complex with the first polynucleotide-containing species, classified in class 514, subclass 44.

- IV. Claims 56, 6, and 64, drawn to microparticles comprising a biodegradable polymer, a cationic surfactant, a first polynucleotide-containing species, and additional microparticles comprising a biodegradable polymer with an immunological adjuvant adsorbed on the surface, classified in class 514, subclass 44.
- V. Claims 57, 63, and 64, drawn to microparticles comprising a biodegradable polymer, a cationic surfactant, a first polynucleotide-containing species, and additional microparticles comprising a biodegradable polymer and an immunological adjuvant entrapped within the additional microparticles, classified in class 514, subclass 44.

Claims 1-18, 27-31, 34-48, 50, 52-55, 58-62, and 69 link(s) inventions I-V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-18, 27-31, 34-48, 50, 52-55, 58-62, and 69. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116;
amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

In addition to the above:

The presently pending linking claims 4-18, 27-30, 36, 43-45, 69 are generic to the following disclosed patentably distinct species:

- A. Polyhydroxy butyric acid, polycaprolactone, polyorthoester, polyanhydride, polycyanoacrylate (claim 4), poly(L-lactide), poly (D,L-lactide or poly(lactide-co-glycolide (claim 6);
- B. Immunological adjuvant (claim 7), a polypeptide-containing antigen (claim 9) or a vector construct that encodes the polypeptide-containing antigen (claim 10);

In addition to the above:

1. Should vector construct encoding a polypeptide-containing antigen be elected for prosecution, a further species election is required, as follows:
 - RNA vector (claim 11), DNA vector (claim 12);

Should DNA vector be elected for prosecution, Applicant is requested to elect one specific species of the following: a plasmid (claim 13) or RNA-virus-based plasmid (claim 14).

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Should plasmid be elected for prosecution, Applicant is requested to elect one specific species of the following: p SINCP (claim 60) or pCMV (claim 61).

2. Should polypeptide-containing antigen be elected for prosecution, a further species election is required, as follows:
 - virus, bacterium, fungus, or parasite (claim 16) or tumor (claim 69);

Should virus be elected for prosecution, Applicant is requested to elect one specific species from the following: HIV, hepatitis B, hepatitis C, meningitis B, *Haemophilus influenza* type B, pertussis, diphtheria, tetanus, influenza A (claim 17), HIV gp120, HIV gp140, HIV gp160, HIV p24gag, or HIV p55gag (claim 18).

3. Should immunological adjuvant be elected for prosecution, a further species election is required, as follows:
 - CpG or dsRNA (claim 8).

C. 10 to 30 % (claim 27) or 10-20% (claim 28);

D. 0.1 to 10 wt% (claim 29) or 0.5 to 2 wt% (claim 30);

E. CpG or dsRNA, MF59, E. coli heat-labile toxins, phospholipids, or aluminum salts (claim 36);

F. Th1 (claim 43) or CTL (claim 44) immune response

The species are independent or distinct because they are drawn to distinct compositions that require different searches in the patent and non-patent literature, and a search and examination of anything more than one of the above-designated species would be a serious burden for the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each group A to F as indicated above, even though this requirement is traversed.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. Should the invention of Group I be elected for prosecution, a further species election is required, as follows:

Claims 19, 74, 84, and 85 are generic to the following disclosed patentably distinct species:

- A. Polynucleotide, polypeptide, polysaccharide, hormone, enzyme, immunological adjuvant (claim 19);
- B. CpG, MF59, dsRNA, E. coli heat-labile toxins, phospholipids, or aluminum salts (claim 74) (it is noted that the elected species must correspond to the species elected for claim 36);
- C. immunological adjuvant adsorbed (claim 84) or entrapped (claim 85).

The species are independent or distinct because they are drawn to distinct compositions that require different searches in the patent and non-patent literature, and a search and examination of anything more than one of the above-designated species would be a serious burden for the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each group A to C, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

4. Should the invention of Group II be elected for prosecution, a further species election is required, as follows:

Claims 23, 78, 86, and 87 are generic to the following disclosed patentably distinct species:

- A. Polynucleotide, polypeptide, polysaccharide, hormone, enzyme, immunological adjuvant (claim 23);
- B. CpG, MF59, dsRNA, E. coli heat-labile toxins, phospholipids, or aluminum salts (claim 78) (it is noted that the elected species must correspond to the species electected for claim 36);
- C. immunological adjuvant adsorbed (claim 86) or entrapped (claim 87).

The species are independent or distinct because they are drawn to distinct compositions that require different searches in the patent and non-patent literature, and a search and examination of anything more than one of the above-designated species would be a serious burden for the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each group A to C, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

5. Should the invention of Group III be elected for prosecution, a further species election is required, as follows:

Claims 32, 82, 88 and 89 are generic to the following disclosed patentably distinct species:

- A. The same surfactant species or different surfactant species (claim 32);
- B. CpG, MF59, dsRNA, E. coli heat-labile toxins, phospholipids, or aluminum salts (claim 82) (it is noted that the elected species must correspond to the species electected for claim 36);
- C. immunological adjuvant adsorbed (claim 88) or entrapped (claim 89).

The species are independent or distinct because they are drawn to distinct compositions that require different searches in the patent and non-patent literature, and a search and examination of anything more than one of the above-designated species would be a serious burden for the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each group A to C, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon,

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including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The inventions of Groups I-III are patentably distinct because they are drawn to different compositions that have distinct structures that require different searches in the patent and non-patent literature, and a search and examination of anything more than one of the above-designated inventions would be a serious burden for the examiner.

7. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

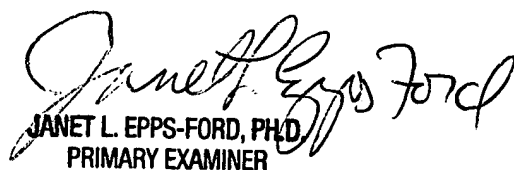
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ileana Popa


JANET L. EPPS-FORD, PH.D.
PRIMARY EXAMINER